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09/847,121	05/02/2001	Richard Rosenbloom	QUIG-1002US	5413

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EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 11

Application Number: 09/847,121
Filing Date: May 02, 2001
Appellant(s): ROSENBLOOM, RICHARD

Kevin J. Dunleavy
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 8, 2002

Art Unit: 1617

(1) *Real Party in Interest*

A statement identifying the real party in interest, Quigley Corporation, is contained in the brief.

(2) *Related Appeals and Interferences*

A statement that no related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct. Claims 1-6, 10, 12-13 and 15 are finally rejected and are appealed.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims appealed herein, i.e., 1-6, 10, 12-13 and 15, do stand or fall together.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(9) Prior Art of Record

5,976,568

Riley

11-1999

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-6, 10, 12-13 and 15 are rejected under 35 U.S.C. 103. This rejection is set forth in the final Office Action, Paper No. 5. The text of this rejection is reproduced herein below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 10, 12-13 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (USPN 5,976,568), of record in the previous office action .

Riley (US 5,976,568) discloses an oral daily supplement composition comprising Vitamins A, D, E, C (Buffered Calcium Ascorbate, Ascorbic Acid and Ascorbyl Palmitate) and quercetin, see claim 2. Riley (US 5,976,568) also discloses an oral daily supplement composition comprising vitamins A, C, D3 and E, see claim 3. See also Table II columns 25 and 28.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an amount affective to promote nerve growth of a vitamin D3 derivative, ascorbyl palmitate and quercetin in a single topical composition.

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One of ordinary skill in the art would have been motivated to incorporate the Riley composition in a topical composition since interconversion of dosage forms is within the skill of the artisan.

(11) Response to Argument

Note that the limitation "topical", which was added to claim 2 after the issuance of the first office action of July 18, 2001 (Paper No. 2) was deleted in the after final amendment of April 11, 2002 (Paper No. 4). The final office action therefore addresses a "topical" formulation. The claims as appealed do not include this limitation. Note that the deletion of topical strengthens the obviousness rejection herein.

A. The difference between a composition and an oral daily dosage form is no more than the difference between taking one instead of two tablets.

Appellant first argues that the prior art of record, Riley, teaches distinct modular formulations, and not a single composition comprising vitamins A,C, D, E, and quercetin. Note that Riley's distinct modular formulations need not be taken separately. In fact, Riley teaches that these modular formulations can be taken together. Riley in relevant part at col. 6, lines 40-54 teaches:

"It should also be understood that Modules 1-3 of the present invention may be administered together [...] in any suitable combination [...]. It is believed, however, that the benefits of modules 2 and 3 are maximized when Module 2 is taken concomitantly with Module 1 and when Module 3 is taken concomitantly with Modules 1 and 2."

As quoted herein immediately above, Riley teaches that it is best if Modules 1-3 are taken concomitantly. If one were to consider each module as a dosage form such as a tablet, following the teaching of Riley one would take the three tablets (Modules 1-3) concomitantly.

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Appellant then argues that taking the modular formulations together does not teach the Skilled Artisan to make a single composition comprising the ingredients of Modules 1-3. In essence, the appellant is arguing that the difference between the instant claims and Riley's teachings is that Riley teaches a modular formulation comprising Vitamins A,C, D, E and quercetin in more than one tablet while the appellant teaches Vitamins A,C,D,E and quercetin in a single tablet.

Appellant further argues that the Skilled Artisan would not be motivated to select quercetin and combine it with the ingredients of the compositions of another module to arrive at the instant invention. Note that as quoted above Modules 1-3 are best administered concomitantly in which case all the ingredients claimed herein would be administered at once. Moreover, given that the instant claims recite the open transitional phrase "comprising", the Skilled Artisan need not pick and choose as all the ingredients taught in Riley's modular formulations can be in the instant composition. In other words, the transitional phrase, "comprising" does not exclude any of the additional ingredients (i.e., ingredients other than vitamins A, C, D, E and quercetin) listed in the modular formulations of Riley.

Appellant argues that the Skilled Artisan would not mix the ingredients from different modules of Riley, because Riley is concerned with vitamin-vitamin and vitamin-mineral interactions. Appellant cites col. 10, lines 46-51. Note that in col. 10, Riley merely states the considerations in designing its particular modules. Also note that Riley specifically teaches many add-on formulations that can be taken with Module 1:

"The add-on modules of the formulation allow the Module 1 AM/PM formula, Module 2, one of the variations of Module 3, and Module 4, to be taken as may be indicated." col. 8, lines 15-18.

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Given these particular teachings of Riley, the Skilled artisan would indeed be motivated to combine the different modular formulations of Riley. Note that the interconversion of dosage forms, i.e., the conversion of two-three modular formulations into a single composition is within the skill of the artisan, and is therefore obvious.

B. The Skilled Artisan in possession of the teachings of Riley at the time the invention was made would have arrived at the instant invention because the instant composition is an obvious modification of Riley's modular formulations.

The appellant lists the differences between Riley and the instant claims. In enumerating these differences appellant relies on the teachings of a single claim in Riley. Note that the teachings of the reference are not limited to claim 2. The reference should be taken as a whole and all of its teachings must be considered.

Appellant states that the particular form of vitamin D, vitamin D₃, is not taught in Riley. Vitamin D₃ is indeed taught in Riley, see for example Tables II and III, cols. 25-28 wherein the particular forms of each vitamin employed in the compositions are specified. Further appellant argues that quercetin is an optional ingredient of claim 2 because its amount can vary from 0-500 mg. Note that particular amounts of quercetin are taught in tables II and III, see Module 3 for example. Appellant also argues that ascorbyl palmitate is not taught as the preferred form of vitamin C or in claim 2. Note that ascorbyl palmitate is specifically taught in Tables II and III, cols. 25-28. Appellant finally argues that the particular amounts recited in the instant claims are not taught in Riley. Note that amounts disclosed in Riley (i.e., 400 IU of vitamin D, 0-500 mg of quercetin and 20-1000 mg of vitamin C per day per subject) read on the claimed amounts herein (i.e., 6-14.3 IU/Kg of vitamin D, 13-21.4 mg/Kg of quercetin and 11-28.6 mg/Kg of ascorbyl palmitate). Appellant argues that the particular amount of ascorbyl palmitate is not taught in

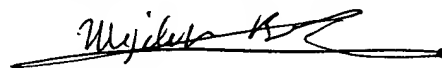
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Riley. Riley teaches that 100 mg-600 mg of Vitamin C in the form of buffered calcium ascorbate, ascorbic acid and ascorbyl palmitate is employed in its modular fomulation, see Tables II and III. Riley further teaches tha Vitamin C can be employed in the amount of 20 mg to 1000 mg in its modular formulations, see claim 2 for example. Assuming *arguendo* that the wide range disclosed in Riley does not specifically cover the amount of ascorbyl palmitate in the instant claims, the optimization of result effective parameters, e.g., amounts, is within the skill of the artisan, and is therefore obvious.

Appellant argues that Riley does not teach an effective amount of quercetin. Note that the optimization of result effective parameters, e.g., amounts, is within the skill of the artisan, and is therefore obvious.


For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



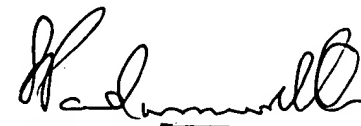
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